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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Rudiger Ridder, *et al.*

Appl. No. 10/633,484

Filed: July 31, 2003

For: METHOD FOR SOLUTION BASED
DIAGNOSIS

Art Unit: 1632

Examiner: Not Yet Assigned

Atty. Docket: 05033.0003.00US00

Confirmation No. 6405

Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted

to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120.

1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
 - ☐ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - c. Before the mailing date of a first Office Action on the merits;
 - ☐ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

- ☐ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or
 - ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but

on or before payment of the Issue Fee. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i), and


- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05033.0003.00US00.

Respectfully submitted,

Date: January 7, 2004


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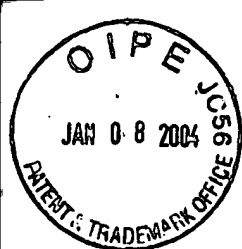
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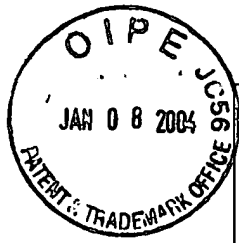
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary) PTO FORM 1449	ATTY. DOCKET NO. 05033.0003.00US00	APPLICATION NO. 10/633,484
	APPLICANT Ridder, <i>et al.</i>	
	FILING DATE July 31, 2003	GROUP 1632

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	1.	2001/0039023	11.08.01	Schubert, Walter			
	2.	2002/0086288	07.04.02	Bird, <i>et al.</i>			
	3.						
	4.						

FOREIGN PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	5.	EP 0 723 156	06.12.95	Europe				
	6.	WO 99/04238	14.07.98	PCT				
	7.	EP 1 217 377	05.12.01	Europe				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)		
	8.	Betticher, <i>et al.</i> , "Prognostic significance of CCND1 (cyclin D1) overexpression in primary resected non-small-cell lung cancer", <i>British J. of Cancer</i> 73: 294-300 (1996)
	9.	Browne, <i>et al.</i> , "Analysis of the L1 Gene Product of Human Papillomavirus Type 16 by Expression in a Vaccinia Virus Recombinant", <i>J. gen. Virol.</i> , 69: 1263-73 (1988)
	10.	Carayol, <i>et al.</i> , "NK cells differentiated from bone marrow, cord blood and peripheral blood stem cells exhibit similar phenotype and functions", <i>Eur. J. Immunol.</i> 28: 1991-2002 (1998)
	11.	Cattoretti, <i>et al.</i> , "Monoclonal antibodies against recombinant parts of the Ki-67 antigen (MIB 1 and MIB 3) detect proliferating cells in microwave-processed formalin-fixed paraffin sections", <i>Journal of Pathology</i> , 168: 357-363 (1992)
	12.	Chilton, <i>et al.</i> , "Estrogen Regulation of the Central Enzymes Involved in O- and N-Linked Glycoprotein Assembly in the Developing and the Adult Rabbit Endocervix", <i>Endocrinology</i> , 123(3): 1237-44 (1988)
	13.	de Boer, <i>et al.</i> , "Changing Roles of Cadherins and Catenins during Progression of Squamous Intraepithelial Lesions in the Uterine Cervix", <i>American Journal of Pathology</i> , 155(2): 505-15 (1999)
	14.	Di Loreto <i>et al.</i> , "Different binding to squamous and columnar epithelium of the uterine cervix as a marker of epithelial differentiation", <i>Bas. Appl. Histochem.</i> 31: 143-52 (1987)
	15.	Epenetos, <i>et al.</i> , "Use of Two Epithelium-Specific Monoclonal Antibodies for Diagnosis of Malignancy in Serous Effusions", <i>The Lancet</i> , 1004-7 (1982)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.


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GROUP

1632

16.	Geradts, <i>et al.</i> , "Immunohistochemical Detection of the Cyclin-dependent Kinase Inhibitor 2/Multiple Tumor Suppressor Gene 1 (CDKN2/MTS1) Product p16 ^{INK4A} in Archival Human Solid Tumors: Correlation with Retinoblastoma Protein Expression", <i>Cancer Research</i> 55: 6006-11 (1995)
17.	Grundhoefer, <i>et al.</i> , "Determination of Liquid-Based Cervical Cytology Specimen Adequacy Using Cellular Light Scatter and Flow Cytometry", <i>Cytometry (Communications in Clinical Sytometry)</i> , 46: 340-4 (2001)
18.	Guillou, <i>et al.</i> , "Squamous Cell Carcinoma of the Lung in a Nonsmoking, Monirradiated Patient with Juvenile Laryngotracheal Papillomatosis", <i>The American Journal of Surgical Pathology</i> , 15(9) 891-8 (1991)
19.	Hamid, <i>et al.</i> , "Detection of Human Probombesin mRNA in Neuroendocrine (Small Cell) Carcinoma of the Lung", <i>Cancer</i> , 63:266-71 (1989)
20.	Harada, <i>et al.</i> , "Phenotypic Difference of Normal Plasma Cells from Mature Myeloma Cells", <i>Blood</i> , 81(10): 2658-63 (1993)
21.	Heid, <i>et al.</i> , "Cell type-specific desmosomal plaque proteins of the plakoglobin family: plakophilin 1 (band 6 protein)", <i>Differentiation</i> , 58: 113-31 (1994)
22.	Hermann, <i>et al.</i> , "Reduced LAK Cytotoxicity of Peripheral Blood Mononuclear Cells in Patients with Bladder Cancer: Decreased LAK Cytotoxicity Caused by a Low Incidence of CD56+ and CD57+ Mononuclear Blood Cells
23.	Hirama, <i>et al.</i> , "p16 (CDKN2/Cylin-dependent Kinase-+ inhibitor/Multiple Tumor Suppressor-1) Gene Is Not Altered in Uterine Cervical Carcinomas or Cell Lines", <i>Modern Pathology</i> , 9(1) 26-31 (1996)
24.	Iftner, <i>et al.</i> , "Involvement of Human Papillomavirus Type 8 Genes E6 and E7 in Transformation and Replication", <i>Journal of Virology</i> , 62(10): 3655-61 (1988)
25.	Jones, <i>et al.</i> , "Detection of T and B Cells in Many Animal Species Using Cross-Reactive Anti-Peptide Antibodies", <i>The Journal of Immunology</i> , 150: 5429-35 (1993)
26.	Kelley, <i>et al.</i> , "CDKN2 in HPV-Positive and HPV-Negative Cervical-Carcinoma Cell Lines", <i>Int. J. Cancer</i> , 63: 226-30 (1995)
27.	Kim, <i>et al.</i> , "Absence of p15 ^{INK4B} and p16 ^{INK4A} Gene Alterations in Primary Cervical Carcinoma Tissues and Cell Lines with Human Papillomavirus Infection", <i>Gynecologic Oncology</i> , 70: 75-9 (1998)
28.	Kim, <i>et al.</i> , "Underexpression of Cyclin-Dependent Kinase (CDK) Inhibitors in Cervical Carcinoma", <i>Gynecologic Oncology</i> , 71: 38-45 (1998)
29.	Klaes, <i>et al.</i> , "Overexpression of p16 ^{INK4A} as a Specific Marker for Dysplastic and Neoplastic Epithelial Cells of the Cervix Uteri", <i>Int. J. Cancer</i> , 92: 276-284 (2001)
30.	Koch, <i>et al.</i> , "Specificity of antibodies to the purified Con A acceptor glycoproteins of cultured tumour cells", <i>Br. J. Cancer</i> , 53: 13-22 (1986)

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APPLICATION NO.

10/633,484

APPLICANT

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July 31, 2003

GROUP

1632

31.	Kommos, <i>et al.</i> , "Inhibin- α , CD99, HEA125, PLAP, and Chromogranin Immunoreactivity in Testicular Neoplasms and the Androgen Insensitivity Syndrome, <i>Human Pathology</i> , 31(9): 1055-61 (2000)
32.	Larsson, <i>et al.</i> , "Tissue Plasminogen Activator and Urokinase in Normal, Dysplastic and Cancerous Squamous Epithelium of the Uterine Cervix, <i>Thrombosis and Haemostasis</i> , 58(3): 822-6 (1987)
33.	Latza, <i>et al.</i> , "Ber-EP4: new monoclonal antibody which distinguishes epithelia from mesothelia", <i>J. Clin Pathol</i> , 43: 213-9 (1990)
34.	Mason, <i>et al.</i> , "Rapid Communication", <i>American Journal of Pathology</i> , 136(6) 1215-22 (1990)
35.	Mendoza-Rodriguez, <i>et al.</i> , "El gen supresor de tumores p53: mecanismos de acción en la proliferación y muerte celular, <i>Rincón Del Residente</i> , 53(3): 266-73 (2001)
36.	Milde-Langosch, <i>et al.</i> , "P16/MTS1 and pRB expression in endometrial carcinomas", <i>Virchows Arch</i> , 434: 23-8 (1999)
37.	Milde-Langosch, <i>et al.</i> , "p16/MTS1 Inactivation in Ovarian Carcinomas: High Frequency of Reduced Protein expression Associated with Hyper-Methylation or Mutation in Endometroid and Mucinous Tumors", <i>Int. J. Cancer</i> , 79: 61-5 (1998)
38.	Mistretta, <i>et al.</i> , "Isolation of a Carcino-Embryonic-Antigen (CEA) from a Liver Metastasis of Primary Adenocarcinoma of the Colon and Preparation of the Specific Antiserum", <i>Specialia</i> , 1209-10 (1974)
39.	Mujica ven Herckenrode, <i>et al.</i> , "Antibodies specific for HeLa glycoprotein antigens are also specific for human endocervical epithelium, <i>Br. J. Cancer</i> , (1988)
40.	Nair, <i>et al.</i> , "Involucrin and Tumor Progression in the Uterine Cervix", <i>Pathobiology</i> , 64: 333-8 (1996)
41.	Nuovo, <i>et al.</i> , "In situ detection of the hypermethylation-induced inactivation of the p16 gene as a early event in oncogenesis", <i>PNAS</i> , 96(22): 12754-9 (1999)
42.	Pagani, <i>et al.</i> , "Expression of the Gastrin-Releasing Peptide Gene in Carcinomas of the Breast", <i>Int. J. Cancer</i> 47: 371-5 (1991)
43.	Rogers, <i>et al.</i> , "A Monoclonal Antibody Against a CEA-related Antigen Expressed on HT29 Colon Tumour Cells", <i>J. Cancer Clinic. Oncology</i> , 20(10): 1279-86 (1981)
44.	Sano, <i>et al.</i> , "Expression Status of p16 Protein Is Associated with Human Papillomavirus Oncogenic Potential in Cervical and Genital Lesions", <i>American Journal of Pathology</i> , 153(6): 1741-8 (1998)
45.	Sano, <i>et al.</i> , "Immunohistochemical overexpression of p16 protein associated with intact retinoblastoma protein expression in cervical cancer and cervical intraepithelial neoplasia", <i>Pathology International</i> , 48: 580-5 (1998)
46.	Serrano, <i>et al.</i> , "A new regulatory motif in cell-cycle control causing specific inhibition of cyclin D/CDK4", <i>Nature</i> , 366: 704-7 (1993)
47.	Shigemasa, <i>et al.</i> , "p16 Overexpression: A Potential Early Indicator of Transformation in Ovarian

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		Carcinoma", <i>J. Soc. Gynecol Invest.</i> , 4(2): 95-102 (1997)
48.	Shim, <i>et al.</i> , "Profiling of Differentially Expressed Genes in Human Primary Cervical Cancer by Complementary DNA Expression Array", <i>Clinical Cancer Research</i> , 4: 3045-50 (1998)	
49.	Smedts, <i>et al.</i> , "Changing Patterns of Keratin Expression During Progression of Cervical Intraepithelial Neoplasia", <i>American Journal of Pathology</i> , 136(3): 657-68 (1990)	
50.	Smith, <i>et al.</i> , "Cytochemical Demonstration of Oxidative Damage in Alzheimer Disease by Immunochemical Enhancement of the Carbonyl Reaction with 2,4-Dinitrophenylhydrazine", <i>The J. of Histochemistry & Cytochemistry</i> , 46(6): 731-5 (1998)	
51.	Southern, <i>et al.</i> , "Loss of Cytokeratin 14 Expression Is Related to Human Papillomavirus Type and Lesion Grade in Squamous Intraepithelial Lesions of the Cervix", <i>Human Pathology</i> , 32(12): 1351-5 (2001)	
52.	Tam, <i>et al.</i> , "Differential Expression and Cell Cycle Regulation of the Cyclin-dependent Kinase 4 Inhibitor p16 ^{INK4} ", <i>Cancer Research</i> , 54: 1816-20 (1994)	
53.	Tashiro, <i>et al.</i> , "Immunohistochemical Study of Mucin Carbohydrates and Core Proteins in Human Ovarian Tumors", <i>Human Pathology</i> , 25(4): 364-72 (1994)	
54.	van der Poel, <i>et al.</i> , "Can biological markers replace cytосcopy? An update", <i>Current Opinion in Urology</i> , 11:503-9 (2001)	
55.	Versura, "Detection of mucus glycoconjugates in human cervical epithelium by lectin-colloidal gold technique in transmission electron microscopy", <i>Bas. Appl. Histochem.</i> , 32: 219-27 (1988)	
56.	Waseem, <i>et al.</i> , "Monoclonal antibody analysis of the proliferating cell nuclear antigen (PCNA) - Structural conservation and the detection of a nucleolar form", <i>J. of Cell. Science</i> , 96: 121-9 (1990)	
57.	Wong, <i>et al.</i> , "Methylation of p16 ^{INK4A} in primary gynecologic malignancy", <i>Cancer Letters</i> , 136: 231-5 (1999)	
58.	Wong, <i>et al.</i> , "p16 ^{INK4} and p15 ^{INK4B} Alterations in Primary Gynecologic Malignancy", <i>Gynecologic Oncology</i> 65: 319-24 (1997)	
59.	Zimmer, <i>et al.</i> , "Proliferating Cell Nuclear Antigen (PCNA) in Atypical and Malignant Meningiomas", <i>Path. Res. Pract.</i> 188: 951-8 (1992)	

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